DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2015

Beeken Biomedical
Mr. Richard Kendall
President and Chief Executive Officer
127 West Hargett Street, Suite 300
Raleigh, North Carolina 27601

Re: K142363
Trade/Device Name: NuStat Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 7, 2014
Received: November 21, 2014

Dear Mr. Richard Kendall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142363

Device Name
NuStat Hemostatic Dressing

Indications for Use *(Describe)*
NuStat is indicated to temporarily control bleeding in minor cuts, lacerations, punctures, abrasions and incisions.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142363

Device Name
NuStat XR Hemostatic Dressing

Indications for Use *(Describe)*
NuStat XR is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions and incisions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Summary Prepared:	August 22, 2014	
510(k) Owner:	Beeken Biomedical 127 West Hargett St., Suite 300 Raleigh, NC 27601	
Contact Person:	Richard Kendall President and CEO (919) 267-3428 rkendall@beekenbiomedical.com	
Device Name:	Device Name:	NuStat®
	Trade Name:	NuStat® and NuStat® XR
	Common Name:	Hemostatic Wound Dressing
	Classification:	Wound Dressing, Drug
	Class:	Unclassified
	Product Code:	FRO
Predicate Device(s):	Primary Predicate	
	K072890	Stasilon FR™ This device has not been subject to a design-related recall.
	Secondary Predicate	
	K102546	ChitoGauze™ XR This device has not been subject to a design-related recall.
Device Description:	The NuStat® range of hemostatic wound dressings are textiles composed of continuous filament silica and bamboo cellulose. This submission adds a radiopaque filament to the NuStat XR models of the legally marketed dressing. The dressings are produced in various sizes to accommodate different wound sizes, ranging from a width of 2” to 8” and length of 2” to 60”. The dressings are either z-folded or rolled into a medical grade Tyvek pouch which is then sterilized using gamma irradiation to a SAL of 10^{-6}. The	

	NuStat® range of hemostatic wound dressings have a number of hemostatic properties which enhance the ability of the dressing to temporarily control bleeding. The cellulose and continuous filament silica influence the contact activation pathway of the coagulation cascade by absorbing blood fluids, resulting in the localized concentration of platelets and clotting factors. The negatively charged fibers of the continuous filament silica simulate the negative ions secreted by activated platelets, which further influence the coagulation cascade. The radiopaque element allows for detection via x-ray.
Statement of Intended Use:	(Over-The-Counter Use): NuStat® is indicated to temporarily control bleeding in minor cuts, lacerations, punctures, abrasions and incisions. (Prescription Use): NuStat® XR is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions and incisions.
Comparison of Technological Characteristics with Predicate Devices:	NuStat® range of dressings are technologically identical to the currently marketed predicate Stasilon FR device (K072890). The addition of the radiopaque filament to the dressing is the similar type of filament in the predicate ChitoGauze XR (K102546) and does not affect the fundamental scientific technological characteristics of the original Stasilon FR. NuStat® dressings and both predicates are hemostatic wound dressings. All three are substantially equivalent in that they contain a hemostatic agent that functions to temporarily control bleeding. NuStat® dressings and Stasilon FR are identical; the hemostatic agent is continuous filament silica, which triggers an electrostatic interaction when in contact with blood to promote clotting. ChitoGauze XR uses a different hemostatic agent, chitosan, which is a polymer that also works by electrostatic interaction to promote clotting. Although the hemostatic components are different, their mechanism of action and outcome is substantially equivalent.
Performance Data:	The biocompatibility evaluation for NuStat® dressings was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO 10993, ‘Biological Evaluation of Medical Device Part 1: Evaluation and Testing’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1L Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of

testing included the following tests as determined for an article determined to be a surface device in contact with breached or compromised surfaces with a prolonged contact duration:

- Cytotoxicity
- Sensitization
- Irritation

A sterility validation for NuStat® was completed following ISO 11137:2006 requirements to demonstrate a 10^{-6} SAL using the VD_{max}^{25} method.

The radiopacity of the radiopaque filament in NuStat® XR was determined via testing performed in accordance with ASTM F640-07 Method C (Standard Test Methods for Determining the Radiopacity for Medical Use). The product was found to be equivalent to the radiopacity of 1.73 ± 0.13 mm thickness 99+% 110 alloy aluminum sheet and was therefore determined to be acceptable.

In vivo and in vitro testing to evaluate the efficacy of the NuStat® range of dressings was not required as the addition of a radiopaque element does not affect the performance of the device as a hemostatic wound dressing. The results of bench safety testing indicate that the new device is as safe as the predicate devices.

Assessment of Clinical Data: Based upon the substantial equivalence determination for the predicate devices, no clinical data was required for evaluation of NuStat® dressings.

Overall Conclusions: Based on the indications for use, technological characteristics, and comparison to predicate devices, the NuStat® range of hemostatic wound dressing is demonstrated to be substantially equivalent to the predicates and is safe and effective for its intended use.